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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/563,078	06/08/2006	Jianming Chen	601/5	6889

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GIBSON & DERNIER L.L.P.
900 ROUTE 9 NORTH
SUITE 504
WOODBRIDGE, NJ 07095

EXAMINER	
WESTERBERG, NISSA M	
ART UNIT	PAPER NUMBER
1618	
MAIL DATE	DELIVERY MODE
07/09/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/563,078	CHEN ET AL.	
	Examiner	Art Unit	
	Nissa M. Westerberg	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 April 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 - 3, 5 - 10* is/are pending in the application.

4a) Of the above claim(s) *5, 8 - 12, 15 - 20* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 - 3, 6, 7, 13, 14* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on April 30, 2009 has been entered.

Claim Objections

2. Claim 14 is objected to under 37 CFR 1.75 as being a substantial duplicate of claim 13. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

3. Claim 6 is objected to because of the following informalities: there is a misspelling present in line 6 of this claim in the term “cross-linked polyvinylpyrrolodione”. Appropriate correction is required.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1, 3, 4, 5, 13 and 14 were rejected under 35 U.S.C. 102(b) as being anticipated by Okada et al. (US 6,455,053). This rejection is MAINTAINED for the reasons of record set forth in the Office Action mailed January 30, 2009 and those set forth below.

Applicant traverses this rejection on the grounds that claimed drop pills are remarkable different from the rapidly dissolving solid preparation of Okada et al. A table comparing the structure and properties (structure, density, etc.) of drop pills versus the preparation of Okada et al. was provided. Applicant considers that the different preparing methods result in different structure and properties of the products of claim 1.

These arguments are unpersuasive. Claim 1 has been amended so that it is a product-by-process claim. As discussed previously, the product of a product-by-process claims cannot be the same or obvious from a product in the prior art. Applicants have not presented any evidence that the products are not only not the same but are also not obvious. Arguments without factual support are mere allegations and are not found to be persuasive.

6. Claims 1, 3, 13 and 14 are rejected under 35 U.S.C. 102(b) as being anticipated by DuRoss (US 5,075,291).

DuRoss discloses compositions comprised of sorbitol as the pharmaceutically acceptable matrix adjuvant and a pharmaceutical active ingredient such as phenylpropanolamine hydrochloride (examples 1 and 3, col 6, ln 50 onwards) or cimetidine (example 5, col 9, ln 34 – 68). Both of these active ingredients are chemically synthesized drugs. In example 7 (col 10), 450 parts of sorbitol are combined with 50 parts of phenylpropanolamine hydrochloride (PPH), so the ratio of matrix adjuvant to pharmaceutical active ingredient is in the range of 1:0.1 to 1:1.

Claim 1 recites the process by which the material prepared, namely dripping a solution of the matrix adjuvant and active ingredient into a coolant, a process which requires the material to start out in a liquid form. "[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) (citations omitted) **MPEP 2113**. DuRoss prepares a hot solution of sorbitol and active ingredient that is either extruded into a strip on a cooled belt (col 7, ln 1 – 5) or onto trays and then cooled (vol 8, ln 62 – 64). Both the cited art and the instant claimed teaches a process of making in which a liquid solution of pharmaceutical matrix

is heated and then cooled. Therefore, the products produced by the processes are the same.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

9. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

10. Claims 1 – 3, 6, 7, 13 and 14 were rejected under 35 U.S.C. 103(a) as being unpatentable over Okada et al. (US 6,455,053). This rejection is MAINTAINED for the reasons of record set forth in the Office Action mailed January 29, 2009 and those set forth herein.

Applicants traverses this rejection on the grounds that the prior art must discloses, teach or suggest each limitation or at least provide an apparent reason to modify the prior art in the direction of the claimed invention. The drop pills have surprising advantages over the rapidly dissolving preparations of Okada et al. in that they are denser, and harder so are easier to package and transport.

These arguments are unpersuasive. As discussed in greater detail above, the alleged differences in structure and properties of the products of the instant claims and the cited prior art are not sufficient for the withdrawal of this rejection. Similarly, more evidence must be presented in order for the allegation of surprising advantages to be persuasive. Therefore, this rejection is maintained for the reasons of record.

11. Claims 1 – 3, 13 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over DuRoss (US 5,075,291) in view of Okada et al. (US 6,455,053).

DuRoss discloses compositions comprised of sorbitol and a pharmaceutical active ingredient such as phenylpropanolamine hydrochloride (examples 1 and 3, col 6,

ln 50 onwards) or cimetidine (example 5, col 9, ln 34 – 68). Both of these active ingredients are chemically synthesized drugs. In example 7 (col 10), 450 parts of sorbitol are combined with 50 parts of phenylpropanolamine hydrochloride (PPH), so the ratio of matrix adjuvant to pharmaceutical active ingredient in the range of 1:0.1 to 1:1.

DuRoss does not disclose the inclusion an extract of crude drug as the pharmaceutical active ingredient in the composition.

In example 4 of Okada et al., a variety of extracts from various plants with the sugar alcohol mannitol are used in pharmaceutical formulations. Lactose, mannitol, sorbitol and erythritol are disclosed as polysaccharides which are all suitable for use in the compositions (col 6, ln 60 – 63). Dispersants such as partly pregelatinzined starch, powdered acacia (Arabic gum), tragant gum (tragacanth gum), pectin, carrageen gum, xanthan gum, polyvinylpyrrolidone or polyvinyl alcohol can be included in the composition (col 7, ln 24 – 34).

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to prepare a pharmaceutical composition as disclosed in DuRoss and to use an extract of a crude drug as the active ingredient. The person of ordinary skill in the art would have been motivated to do so and reasonably would have expected success as DuRoss and Okada et al. disclose pharmaceutical compositions with high concentration of a sugar alcohol such as sorbitol. The selection and inclusion of other ingredients, such as the dispersants disclosed by Okada et al., is within the skill of one

of ordinary skill in the art to select and include in the composition, to alter the physical properties and dissolution properties of the prepared dosage forms.

Claim 1 recites the process by which the material prepared, namely dripping a solution of the matrix adjuvant and active ingredient into a coolant, a process which requires the material to start out in a liquid form. "[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) (citations omitted) **MPEP 2113**. DuRoss prepares a hot solution of sorbitol and active ingredient that is either extruded into a strip on a cooled belt (col 7, ln 1 – 5) or onto trays and then cooled (vol 8, ln 62 – 64). Both the cited art and the instant claimed teaches a process of making in which a liquid solution of pharmaceutical matrix is heated and then cooled. Therefore, the products produced by the processes are the same.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nissa M. Westerberg whose telephone number is (571)270-3532. The examiner can normally be reached on M - F, 8:00 a.m. - 4 p.m. ET.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jake M. Vu/
Primary Examiner, Art Unit 1618

NMW